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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 17/16, 17/04, 17/064</b>		(11) International Publication Number: <b>WO 97/47246</b>
<b>A1</b>		(43) International Publication Date: 18 December 1997 (18.12.97)
(21) International Application Number: <b>PCT/IL97/00185</b> (22) International Filing Date: 10 June 1997 (10.06.97) (30) Priority Data: 118617                      10 June 1996 (10.06.96)                      IL 119151                      28 August 1996 (28.08.96)                      IL (71) Applicant (for all designated States except US): <b>INFLUENCE MEDICAL TECHNOLOGIES LTD. (IL/IL); 14 Abba Hillel Street, 52522 Ramat Gan (IL).</b> (72) Inventor; and (75) Inventor/Applicant (for US only): <b>SOHN, Ze'ev (IL/IL); Neve Tzuf, 71945 D.N. Modi'in (IL).</b> (74) Agents: <b>COLB, Sanford, T. et al.; Sanford T. Colb &amp; Co., P.O. Box 2273, 76122 Rehovot (IL).</b>		(81) Designated States: <b>AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</b>  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: <b>SUTURE INSERTION DEVICE FOR THE TREATMENT OF URINARY STRESS INCONTINENCE</b>		
(57) Abstract <p>Apparatus and method for inserting a suture thread through a curved channel in a bone. The curved channel is formed by a curved needle, having a head and a shank, driven into the bone at one point and emerging from the bone at another point. The needle preferably includes superelastic material. The needle is inserted into the bone using an insertion tool, into which the needle is loaded and which forces the needle into the bone, either by percussive impact or, alternatively, by drilling into the bone, wherein the head of the needle includes a drill bit. A suture is threaded through the curved channel, and the ends of the suture are tied together to suspend tissue or a sling to the bone. Alternatively, two needles, at least one of which is curved, may be used, wherein each of the needles is adapted to form and be removed from a respective partial channel in the bone, which partial channels meet to form the curved channel, passing through the bone.</p>		

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**SUTURE INSERTION DEVICE FOR THE TREATMENT OF URINARY STRESS INCONTINENCE****RELATED APPLICATIONS**

This application is related to and claims priority from Israel patent application no. 118,617, filed June 10, 1996, and Israel patent application no. 119,151, filed August 28, 1996.

**FIELD OF THE INVENTION**

The present invention relates generally to surgical devices and methods, and specifically to devices and methods for fastening a suture to a bone, particularly useful in treating female urinary stress incontinence.

**BACKGROUND OF THE INVENTION**

Urinary stress incontinence, i.e., the inability to control urination from the bladder, affects more than ten percent of elderly women, as well as many younger women. This condition frequently arises as a result of the bladder neck and proximal urethra moving away from the posterior wall of the pubic bone. Various surgical treatments, known in the art, attempt to correct the condition by returning the bladder and proximal urethra to their normal position.

U.S. patent 5,520,700, whose disclosure is incorporated herein by reference, describes a surgical stapler device and staples for use in treating urinary stress incontinence, as well as a method of using them. The staples are preferably formed of an elastic material, having a normally bent shape. A suture thread is threaded through a hole in the staple, which is then straightened and loaded into the barrel of the stapler. The loaded stapler is inserted into the vagina of a female subject, and the staple is ejected through the vaginal wall into the pubic bone. Once inside the bone, the staple resumes its curved shape, thus anchoring the suture thread in the bone. The ends of the thread remaining outside the bone are then used to secure the bladder neck in its desired position.

The staple described in the above mentioned 5,520,700 patent remains permanently in the bone, to hold the suture thread in place.

Similarly, PCT patent application PCT/US95/16344, filed December 14, 1995, published under publication number WO96/18352, and incorporated herein by reference, describes an improved staple and thread assembly, for surgical use as described above. The staple is made of a shape memory material known in the art, for example a nickel/titanium/vanadium alloy, which is formable, non-elastic and straight at room temperature, outside the body, but elastic and curved at body temperature. The staple thus assumes this curved, elastic state once it is inside the bone, anchoring the thread more securely.

The staple described in the above mentioned PCT patent application comprises a pointed head section and a narrower shank section. The shank section includes two adjoining transverse holes, through which the thread is inserted. The wider head section protects the thread in the

shank section from damage as the staple is inserted into the bone. In addition, the longitudinal axis of the shank section is preferably offset relative the longitudinal axis of the head section, to provide further protection from damage.

PCT patent application no. PCT/US97/02638, filed February 21, 1997, which is assigned to the assignee of the present patent application and whose disclosure is incorporated herein by reference, describes still further improvements to the staple and stapler for use in the above mentioned procedure. This patent application also describes other types of bone anchors and bone screws, which may be inserted into the bone and used for securing suture thread thereto, as well as an improved device for inserting a staple, anchor or screw into the bone.

U.S. patent 5,601,572, which is incorporated herein by reference, describes surgical fasteners, tools and procedures based on superelastic materials. The fasteners include, *inter alia*, curved needles and ring clips, formed of superelastic material, for insertion into soft body tissues. Such fasteners are straightened and loaded into a cannula or other hollow housing, from which they are ejected into the tissue by pushing a piston through the cannula. Once out of the cannula, the fasteners then assume curved shapes useful for fixing or manipulating the soft tissue. The patent discloses that such superelastic fasteners could be passed around a bone and thus used to manipulate the bone, but does not suggest the possibility or provide suitable means for inserting the fasteners into or through the bone itself.

Other surgical methods known in the art for treatment of urinary stress incontinence do not require that a staple, screw or anchor remain in the bone. One such method is the bone fixation technique for needle suspension of the proximal urethra and bladder neck, as described, for example, by Leach in Urology XXXI (May, 1988), pages 388-390, which is incorporated herein by reference. In this method, a needle guiding a suture is driven through the tubercle on one side of the pubic bone. The needle is then removed, leaving the suture in place. A second suture is similarly inserted on the other side of the pubic bone, and the two sutures are then tied transvaginally to suspend the bladder neck. Although this method is felt to be effective in treating incontinence, it requires major, open abdominal surgery to expose the pubic bone and insert the sutures.

Another method for suspending the bladder neck to treat urinary stress incontinence is the pubovaginal fascial sling technique, as described, for example, by Blaivas, *et al.*, in The Journal of Urology 145 (June, 1991), pages 1214-1218, which is incorporated herein by reference. In this method, a strip of endopelvic fascia or other material is dissected and is then passed under the bladder neck or urethra and secured to the abdominal fascia in front of the bladder, to raise or prevent descent of the bladder during strain. Other biological and synthetic materials may be used in place of the dissected human fascia to support the bladder neck, for example Gore-tex manufactured by Gore, Inc., bovine pericardium manufactured by Biovascular, Inc. under the product name Bioguard, or other material such as a porcine graft manufactured by Ethicon, a division of Johnson and Johnson. This sling technique is particularly

useful in treating complicated cases of stress incontinence, such as Type III incontinence (also termed intrinsic sphincteric damage) that are not amenable to treatment by a simple needle bladder suspension, but it involves a complicated procedure and major, open abdominal surgery to dissect and secure the fascia or other materials as described. In addition, the sling procedure is recommended for all types of urinary stress incontinence due to its established long term success rate as a treatment for incontinence.

### SUMMARY OF THE INVENTION

It is an object of the present invention to provide improved devices and methods for inserting and securing a suture thread in a bone.

In one aspect of the present invention, the suture thread is secured in the bone without the need for a staple, screw or anchor of any other type to remain in the bone after insertion.

In another aspect of the present invention, the device for inserting and securing the suture thread includes a lumen, through which a drilling device is used to create a channel in the bone and/or through which the thread may be passed, which lumen remains in the bone so as to secure the thread thereto. Because the thread is secured by the mechanical strength of the bone itself, the device for inserting and securing the thread in the bone may be relatively thin by comparison with staples and other anchoring devices that are normally used for this purpose, such as those described in the above mentioned patent applications and the 5,520,700 patent.

In still another aspect of the present invention, the devices and methods are used in minimally-invasive surgical treatment of urinary stress incontinence.

In preferred embodiments of the present invention, a curved guide needle, having a tip and a shank, is driven into a bone using an insertion tool. The needle creates a curved channel through the bone, including closely spaced entrance and exit holes, wherein the exit hole is generally adjacent to the entrance hole. A suture thread is fed through the channel, and is then tied with tissue in between its two points of exit from the bone so that it secures this tissue to the bone. Preferably, tying the tissue creates a bladder neck suspension, as described hereinbelow.

In some preferred embodiments of the present invention, the needle is withdrawn from the channel, preferably using a grasping and withdrawing tool designed for this purpose. The grasping and withdrawing tool may be combined in a single unit with the insertion tool, or it may be separate therefrom. The suture thread is fed through the channel, preferably with the aid of the needle and simultaneously with the withdrawal of the needle. Alternatively, the thread may be fed through the channel independently of the needle, after the needle has been withdrawn. No staple, screw or other anchor is left behind in the body.

In some preferred embodiments of the present invention, the insertion tool is an insertion gun, which propels the needle into the bone by means of a sharp impact.

In some of these preferred embodiments, the thread is attached to the needle, for example by feeding the thread through one or more holes in the shank of the needle, as described in the above mentioned patent applications and the 5,520,700 patent. Alternatively, the thread is

attached to the needle by crimping the shank of the needle around an end of the thread. The needle is then propelled into the bone using the insertion gun. After insertion, the tip of the needle protrudes through the exit hole. The needle is grasped by its tip and pulled through the exit hole, thus threading the thread through the entire channel. The needle is then detached from the thread, which remains in the bone.

In other preferred embodiments of the present invention, the needle includes a hollow lumen therethrough and has a detachable head, which closes the end of the lumen at the needle's tip. The thread is attached to the head of the needle and passes through the lumen and out the opposite end of the needle. After insertion of the needle, as described above, the head of the needle protrudes through the exit hole. The head is grasped and pulled away from the shank of the needle, preferably using a grasping and detaching tool as described above, pulling the thread after it through the channel. The shank of the needle is then withdrawn from the channel by pulling it back in the direction from which it was inserted.

In such preferred embodiments of the present invention, the head is preferably substantially wider than the shank, so that after the head penetrates through the exit hole, it is caught in place and does not slide back into the channel.

In other preferred embodiments of the present invention, in which the needle has a detachable head, as described above, the shank of the needle is not withdrawn from the channel after detachment of the head. Rather, the shank remains inside the channel, thereby providing a smooth lumen through which the thread is passed and secured.

In still other preferred embodiments, as indicated above, the needle is propelled into the bone without connecting the thread to the needle. After the needle has created the channel through the bone, it is withdrawn, and the thread is threaded through the channel.

In the preceding preferred embodiments of the present invention, the impact of the needle as it creates the exit hole, coming out of the channel, may cause the bone to chip or break near the site of the hole. Therefore, in another preferred embodiment of the present invention, two needles, of which at least one is preferably curved, are propelled into the bone at two adjacent sites. The needles are oriented so that each creates a partial channel in the bone, wherein the partial channels curve toward each other and meet inside the bone to form a single, full channel, entering and exiting the bone. The needles are then withdrawn from the bone, and the thread is threaded through the channel.

In other preferred embodiments of the present invention, the needle comprises curved elastic material and includes a miniature drill bit, as is known in the art, at its tip, such as is used, for example, in flexible cable tooth drillers. The bit is driven by the flexible rotary drive wire passing through a lumen in the shank of the needle. Preferably, the insertion tool comprises a rotary drive mechanism, which is coupled to the drive wire at the end of the shank opposite to the tip.

In order to drive the needle into the bone, the tip of the needle is pressed against the bone surface at a desired location and the rotary mechanism is activated. The rotating drill bit drills the entrance hole through the bone cortex and into the soft medulla of the bone. Within the medulla, the curved shape of the needle causes the tip of the needle to curve back toward the bone cortex, wherein the drill bit then drills the second, exit hole back out of the bone.

Preferably, the needle is then drawn back, out of the bone, through the entrance hole, and the suture thread is fed through the channel that has been drilled in the bone. Preferably, the drill bit has a radial diameter that is comparable to or smaller than the diameter of the needle, so that the drill bit can be drawn back out of the bone in the same direction as the needle. Alternatively, if the diameter of the drill bit is larger than that of the needle, the flexible drive wire is released from the rotary mechanism, so that the drill bit and drive wire may be pulled out together through the exit hole, while the needle is withdrawn through the entrance hole.

Further alternatively, the needle and the rotary drive wire may be detached from the insertion tool and pulled out through the exit hole.

In these preferred embodiments of the present invention, the suture thread is preferably attached to the needle before pulling the needle out of the bone, for example by feeding the thread through a hole in the shank of the needle, as described above, so as to feed the thread through the channel simultaneously with removing the needle.

In other preferred embodiments of the present invention, in which the needle comprises a drill bit at its tip as described above, after the channel has been drilled through the bone, the drill bit and flexible drive wire are detached from the rotary mechanism and pulled out forward through the exit hole. The needle is also detached from the insertion tool, and the tool is removed, leaving the needle inside the channel in the bone. The suture thread is then fed through the now-empty lumen of the needle, which remains inside the bone permanently.

In some preferred embodiments of the present invention, the needle is made of superelastic material known in the art, such as Nitinol. The needle is preferably straightened for loading in the insertion tool, and then curves forcefully as it is ejected out of the tool and into the bone, thus creating the curved channel through the bone. It will be appreciated that these preferred embodiments differ substantially from fasteners and insertion devices described in the above-mentioned U.S. patent 5,601,572, which are capable only of penetrating soft tissue and cannot form curved channels through hard tissue, such as bone.

In other preferred embodiments of the present invention, the needle is made of curved, substantially rigid material. Preferably, the insertion tool has a curved barrel, in order to accommodate the needle and drive it with the required force through the bone.

In some preferred embodiments of the present invention, the needle, thread and insertion tool are used to secure a suture thread to the pubic bone, for treatment of urinary stress incontinence. Preferably, at least two sutures are attached to the bone in this manner, at opposite sides of the urethra, with the distance between each suture hole at each ipsilateral side



of the urethra being 1-4 cm, and are used to tie in place prolapsed tissues so as to suspend the neck of the bladder, substantially as described in the above mentioned patent and patent applications.

Alternatively, at least two sutures, attached to the pubic bone at opposite sides of the urethra, are used in a minimally-invasive sling suspension procedure, to secure the ends of a pubovaginal sling, which has been inserted under and thus suspends the bladder neck and/or the urethra. Preferably, the sling comprises bovine pericardium, or alternatively, Gore-tex fabric or fascia dissected from another part of the subject's body, preferably non-abdominal fascia, so that the entire procedure is performed transvaginally, without any abdominal incision and without substantial vaginal wall or endopelvic fascia dissection. Alternatively, the procedure may be performed by first dissecting the vaginal wall and endopelvic fascia to enter the retropubic space and expose the pubic bone, prior to insertion of the sutures.

Alternatively or additionally, the devices and methods described here may be used in other surgical procedures.

There is therefore provided, in accordance with a preferred embodiment of the present invention, apparatus for inserting a suture thread through a curved channel in a bone, including a curved needle, having a head and a shank; and an insertion tool, into which the needle is loaded, and which forces the needle into the bone, wherein the needle is adapted to form the curved channel, passing through the bone.

Preferably, the needle is further adapted to be removed from the curved channel.

Preferably, the needle includes superelastic material and is substantially straightened when loaded into the tool.

Further preferably, the head of the needle is asymmetrical.

Alternatively, the tool includes a curved barrel, into which the needle is loaded.

Preferably, the needle has a predetermined outer diameter, and the tool includes a generally straight barrel into which the needle is loaded, the barrel having an inner diameter substantially greater than the outer diameter of the needle, such that the needle is partially straightened when loaded into the barrel. The needle is forced into the bone at an angle dependent on the difference between the inner diameter of the barrel and the outer diameter of the needle.

Preferably, the needle includes a hole, through which the thread is inserted. Alternatively, the thread is crimped to the needle.

Preferably, the head of the needle is detachable from the shank, and the shank includes an outer wall, which defines and encloses a lumen therein, through which the thread is passed.

Preferably, the insertion tool is an insertion gun, which propels the needle into the bone by percussive impact.

Alternatively, the head of the needle includes a drill bit, and the insertion tool includes a rotary drive mechanism, which causes the drill bit to rotate, so as to drill the curved channel in

the bone. The drill tip can also have a screw-type driller so as to facilitate bone penetration with no need of applying axial pressure during drilling. Preferably, there is a flexible drive wire within the needle, which couples rotary motion from the drive mechanism to the drill bit. Further preferably, the insertion tool includes a retractable barrel, into which the needle is loaded.

5 There is further provided, in accordance with another preferred embodiment of the present invention, apparatus for inserting a suture thread through a curved channel in a bone, including:

two needles, at least one of which is curved; and

10 one or more insertion tools, into which the two needles are loaded, and which propel the needles into the bone,

wherein each of the needles is adapted to form and be removed from a respective partial channel in the bone, which partial channels meet to form the curved channel, passing through the bone.

Preferably, the at least one curved needle includes superelastic material.

15 Further preferably, the one or more insertion tools include a double-barreled insertion gun.

In a preferred embodiment, one of the two needles includes an eye, through which the other of the needles passes.

20 In a further preferred embodiment, one of the two needles includes a suture passer, which inserts a suture into the channel, where it is received by the other of the two needles. Preferably, the suture passer includes a sleeve and a shaft longitudinally movable within the sleeve, the shaft having a head with an opening therein for receiving the suture, such that by moving the shaft within the sleeve, the suture is grasped in the opening.

25 There is also provided, in accordance with a preferred embodiment of the present invention, a method for inserting a suture thread through a bone, including forming a curved channel through the bone; and inserting the thread through the channel.

Preferably, forming the curved channel through the bone includes drilling through the bone.

30 Additionally or alternatively, forming the curved channel through the bone includes forcing at least one curved needle through the bone and removing the needle from the bone, preferably by pulling all or a part of the needle through the channel in the direction in which it was propelled therinto. Preferably, forcing the needle through the bone includes percussively propelling the needle into the bone.

35 Additionally or alternatively, removing the needle from the bone includes withdrawing all or a part of the needle from the channel in the direction from which it was propelled therinto.

Preferably, the at least one needle includes a head part and a shank part, and removing the needle from the bone includes detaching the head part from the shank part.

Preferably, inserting the thread through the channel includes attaching the thread to the needle.

Alternatively, forming the curved channel includes forcing a curved needle, having a central lumen, through the bone, and inserting the thread through the channel includes passing the thread through the lumen.

Preferably, forming the curved channel through the bone includes forming a channel having generally adjacent entrance and exit holes and following a curved path, connecting the entrance and exit holes, through the medulla of the bone.

In a preferred embodiment, forming the curved channel through the bone includes forming a channel that enters the bone at a predetermined angle substantially different from 90° relative to an outer surface of the bone.

In another preferred embodiment, forming the curved channel includes forming two partial channels, which meet inside the bone. Preferably, forming the two partial channels includes forcing two needles into the bone, at least one of which needles is curved.

Further preferably, inserting the thread through the channel includes passing the thread into one of the two partial channels using a first one of the two needles, and pulling the thread through the channel using a second one of the two needles, most preferably by passing the first one of the needles through an eye in the second one of the needles.

There is moreover provided, in accordance with a preferred embodiment of the present invention, a method for treating incontinence in a female subject, including:

transvaginally inserting first and second suture threads through the pubic bone on the posterior or superior surface of the bone in accordance with the method described above, wherein the first and second suture threads are inserted on opposite sides of the subject's urethra; and

tying together the extremities of each of the threads so as to secure prolapsed tissue or a sling material to the pubic bone, thereby suspending the subject's bladder neck.

There is additionally provided, in accordance with a preferred embodiment of the present invention, a method for treating incontinence in a female subject, including:

transvaginally forming a curved channel, comprising generally adjacent entrance and exit holes and following a curved path, connecting the entrance and exit holes, through the medulla of the pubic bone;

inserting first and second suture threads through the channel on the posterior side of the bone, wherein the first and second suture threads are inserted on opposite sides of the subject's urethra;

inserting a sling transversely below the subject's urethra, so that the ends of the sling are in respective proximity to the first and second sutures in the pubic bone; and

tying the threads, so as to secure the ends of the sling to the pubic bone.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings in which:

### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a schematic illustration of a needle for insertion through a bone, in accordance with a preferred embodiment of the present invention;

Fig. 1B is a schematic illustration of a needle for insertion through a bone, in accordance with another preferred embodiment of the present invention;

Fig. 2A is a schematic, partly sectional illustration of an insertion gun, for insertion of the needle shown in Fig. 1A, in accordance with a preferred embodiment of the present invention;

Fig. 2B is a schematic, cross-sectional representation of the insertion gun shown in Fig. 2A;

Figs. 2C and 2D are schematic, partly sectional illustrations of other insertion guns, in accordance with alternative preferred embodiments of the present invention;

Figs. 3A-3C illustrate schematically, in sectional view, insertion through the bone of the needle shown in Fig. 1A, using an insertion gun as shown in Fig. 2A, and the use of the needle to guide a suture thread through the bone, in accordance with a preferred embodiment of the present invention;

Fig. 4A is a schematic, sectional illustration of a needle for insertion through a bone, in accordance with an alternative preferred embodiment of the present invention;

Fig. 4B illustrates schematically, in sectional view, the use of the needle shown in Fig. 4A, in accordance with a preferred embodiment of the present invention;

Fig. 4C illustrates schematically, in sectional view, an alternative use of the needle shown in Fig. 4A, in accordance with another preferred embodiment of the present invention;

Fig. 5 is a schematic, partly sectional representation of an insertion gun, for creating a channel through a bone, in accordance with yet another preferred embodiment of the present invention;

Fig. 6 illustrates schematically, in partly sectional view, a pair of needles inserted through a bone, in accordance with still another preferred embodiment of the present invention;

Fig. 7A is a schematic, partly sectional illustration of an insertion tool and a needle, having a drill bit at its tip, for drilling a channel through a bone, in a first configuration in which the needle is substantially straight, in accordance with another preferred embodiment of the present invention;

Fig. 7B is a schematic, partly sectional illustration of the insertion tool and needle of Fig. 7A, in a second configuration in which the needle has assumed a curved shape;

Fig. 7C is a schematic, sectional view of a needle similar to the needle of Figs. 7A and 7B, but having a larger drill bit at its tip, in accordance with an alternative preferred embodiment of the present invention; and

Fig. 8 is a schematic, sectional illustration of the use of the tool, needle and drill bit of Figs. 7A and 7B in drilling a channel through a bone;

Fig. 9A is a schematic, sectional illustration showing an initial step in a method using two needles for creating a channel through a bone and passing a suture therethrough, in accordance with a preferred embodiment of the present invention;

Fig. 9B is a schematic side view of one of the needles shown in Fig. 9A;

Figs. 9C and 9D are schematic, sectional illustrations showing ensuing steps in the method of Fig. 9A;

Fig. 10 is a schematic, sectional illustration showing a suture-passing needle, in accordance with a preferred embodiment of the present invention;

Figs. 11A and 11B are schematic, sectional illustrations showing another suture-passing needle, in open and closed configurations, respectively, in accordance with a preferred embodiment of the present invention;

Fig. 12 illustrates schematically, in partly sectional view, the use of an insertion tool in performing a bladder neck suspension procedure, in accordance with a preferred embodiment of the present invention; and

Fig. 13 illustrates schematically the insertion of sutures through the pubic bone of a subject, in accordance with a preferred embodiment of the present invention.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Fig. 1A, which illustrates schematically a needle 20 for use in inserting of a suture thread 22 through a bone of a subject, in accordance with a preferred embodiment of the present invention. Needle 20 comprises a head 24, preferably pointed, and a shank 26. Preferably, head 24 slants inward, as shown in Fig. 1A, so as to facilitate the needle's passage through the bone along a desired curved path, as described hereinbelow. Thread 22 is fastened to shank 26 by crimping the end of the shank opposite head 24, so as to form a crimp 27 that grasps the thread. Alternatively, the thread may be fastened to the needle using any other suitable method known in the art.

Fig. 1B illustrated an alternative preferred embodiment of the present invention, in which a hole 28 is provided in shank 26, through which hole thread 22 is inserted, like a sewing thread through the eye of a needle. Although in Fig. 1B hole 28 is located near the far end of needle 20 from head 24, the hole may alternatively be placed at any suitable point along shank 26. Needle 20 may include additional holes, so that thread 22 may be attached more securely thereto, for example as described in the above mentioned PCT patent application.

Furthermore, as shown in Fig. 1B and described in the above-mentioned PCT patent application, in some preferred embodiments of the present invention, head 24 is generally wider than shank 26, and the shank is preferably laterally offset relative to head 24. These characteristics are generally useful in creating a curved channel through the bone, as will be described below, and in protecting thread 22 from damage as it is pulled through the channel.

Other shapes and configuration of head 24 and shank 26 may also be used, however, including those shown in Fig. 1A and various shapes and configurations described in the 5,520,700 patent and the above mentioned PCT patent applications.

Needle 20 preferably comprises a superelastic alloy, known in the art, for example Nitinol. The needle may be conveniently straightened before insertion into the bone, as will be described below, and will then immediately resume its desired, curved shape inside the bone, due to the alloy's extremely high elasticity. Alternatively, needle 20 may be made of a normally elastic metal, such as stainless steel, in which case its desired, curved shape is maintained at all times.

Fig. 2A is a schematic, partly sectional illustration of an insertion gun 30, in accordance with a preferred embodiment of the present invention. Gun 30 includes a propulsion mechanism 32 and a barrel 34, into which needle 20 has been inserted. It will be understood that gun 30 is intended for use with superelastic needles, as described above, which are straightened for insertion into barrel 34. Needle 20 shown in Fig. 2A includes hole 28, through which thread 22 is fed, and barrel 34 includes a slot 36 to allow the thread to pass forward with the needle.

Fig. 2B shows a cross-sectional view of barrel 34, illustrating the position of slot 36.

Mechanism 32 preferably operates substantially as described in the 5,520,700 patent, or alternatively as described in the above mentioned PCT patent applications. When mechanism 32 is actuated by a surgeon, ejector pin 38 is propelled forcefully forward into barrel 34, driving needle 20 rapidly out of the barrel and into the bone.

Fig. 2C is a schematic, partly sectional illustration of another insertion gun 40, similar in operation to gun 30, but having a curved barrel 42. Gun 40 is intended primarily for use with needles that are not superelastic, since barrel 42 allows such needles to be maintained and inserted without substantially altering the needles' curved shape. Gun barrels having other shapes and curvatures, for example intermediate between the straight barrel shown in Fig. 2A and the fully curved barrel in Fig. 2C, may also be used.

Needle 20 in Fig. 2C has thread 22 attached to crimp 27, as was discussed in reference to Fig. 1A. The thread is fed back through a lumen 43 in ejector pin 38 and then through a tube 45 or other suitable channel in mechanism 32. In this configuration, there is no need for a slot in barrel 42 to allow passage of the thread. It will be understood that ejector pin 38 and mechanism 32 shown in Fig. 2A for use with straight barrel 34 may be similarly constructed and configured for passage of the thread therethrough.

Fig. 2D is a schematic, partly sectional illustration showing another inserting gun 41, in accordance with an alternative preferred embodiment of the present invention. Needle 20, preferably of the superelastic type described above, is loaded into barrel 34 of the gun. Although the needle is shown in this figure without suture 22 attached thereto, it will be understood that the suture may be attached and passed through the barrel in the manner shown either in Fig. 2A

or Fig. 2C above, or in any other suitable manner. Gun 41 includes propulsion mechanism 32 and ejector pin 38, as described with reference to gun 30 shown in Fig. 2A.

Gun 41 differs from gun 30, however, in that barrel 34 of gun 31 is substantially wider than the diameter of needle 20. Consequently, needle 20 is not entirely straightened when inserted into the barrel, and when the gun is actuated, needle 20 will be propelled into the bone at an angle relative to the axis of the barrel, rather than straight in, as in the case of gun 30. For example, if needle 20 has a diameter of 1.5 mm, and barrel 34 has an inner diameter of 2.0 mm, the needle will enter the bone at approximately a 45° angle to the barrel direction. In either case, whether fired by gun 30 or gun 41, needle 20 will form a curved channel in the bone, as described below. By using a wider barrel, as in gun 41, the entry angle of the needle into the bone may be varied, so that the channel enters the bone at a substantially non-perpendicular angle relative to the bone surface. Different diameters of barrel 34 will give different entry angles.

Figs. 3A-3C illustrate schematically, in sectional view, the stages of insertion of thread 22 through a bone 50, preferably the pubic bone of a female subject undergoing surgical treatment for urinary stress incontinence.

As shown in Fig. 3A, needle 20 is loaded into barrel 34 of gun 30 (shown in Fig. 2A), and the surgeon places the barrel firmly in contact with the surface of bone 50. The gun is then fired, and head 24 is driven through bone 50, creating a channel 52 therethrough, as shown in Fig. 2B. As needle 20 exits the gun, its superelasticity causes shank 26 to rapidly and forcefully resume its normal curved shape. As a result, head 24 curves through bone 50, finally creating and protruding through an exit hole 54 therein.

As illustrated in Fig. 3C, the surgeon then grasps head 24 and pulls needle 20 through channel 52 and out exit hole 54. Thread 22 is likewise pulled by needle 20 through the channel, so that after the needle has been removed, the thread remains in the channel, protruding from both exit hole 54 and entry hole 56. Thread 22 is then preferably used to tie the subject's periurethral tissue or a sling-type strip material in place, as described in the 5,520,700 patent and the above mentioned PCT patent applications. This suture fixation to the bone and the resulting bladder neck suspension can be performed through the vagina without dissecting to the pubic bone surface or, alternatively, by opening of the vaginal mucosa and revealing the pubic bone.

Fig. 4A is a schematic, sectional representation of another needle 60 for creating a channel through a bone and inserting thread 22 therethrough. Needle 60 comprises a curved shank 64 and a detachable head 62. Shank 64 comprises an outer wall 65, defining and enclosing a lumen 66 therein. Head 62 includes a hole 68, through which thread 22 is inserted and then passed through lumen 66, protruding through an opening 70 at the rear end of needle 60.

Fig. 4B schematically illustrates, in sectional view, the use of needle 60 in inserting thread 22 through bone 50. Needle 60 is first propelled through the bone, creating channel 52

therethrough, substantially as illustrated with reference to needle 20 in Figs. 3A and 3B and described above. The surgeon then grasps head 62, which protrudes through exit hole 54, and pulls it out through the hole, simultaneously detaching the head from shank 64. Thread 22, held in hole 68, is pulled through lumen 66, following head 62. Shank 64 is pulled back and out of channel 52 through entrance hole 56. Head 62 and shank 64 are finally detached from thread 22, leaving the thread in place in channel 52, so that it may be used to tie the bladder neck as described above or for other surgical purpose.

The preferred embodiment of the present invention shown in Figs. 4A and 4B will be useful in alleviating difficulties that may arise in passing needle 20 forward through channel 52. Such difficulties could necessitate the use of excessive force, causing the needle to break, or causing damage to thread 22 or bone 50.

Fig. 4C illustrates an alternative preferred embodiment of the present invention, in which shank 64 of needle 60 remains inside channel 52, rather than being withdrawn therefrom as shown in Fig. 4B. Thread 22 thus remains inside lumen 66, which provides a smooth passageway through which the thread can be passed and fastened.

Alternatively, in still other preferred embodiments of the present invention, an unthreaded needle, such as needle 20 or needle 60 for example, is inserted through bone 50, as shown in Figs. 3A-3C or Fig. 4B, respectively, without attaching thread 22 thereto. It will be understood that other types of needles, without a crimp, hole or lumen for attaching the thread, may similarly be used for this purpose. After the needle has formed channel 52 and been removed from the bone, thread 22 is threaded through the channel, for example using a thin, elastic guide wire, known in the art. These preferred embodiments are useful in reducing the complication involved in attaching thread 22 to needle 20 or needle 60 before insertion of the needle into the bone, and in reducing the likelihood of damage to the thread during insertion.

Fig. 5 schematically illustrates an insertion gun 74, which is similarly used to form channel 52, through which thread 22 is inserted after removal of the gun, in accordance with another preferred embodiment of the present invention. Gun 74 includes an integral, ejectable needle 76, which is driven into the bone by mechanism 78. Needle 76 is then withdrawn from the bone prior to threading thread 22 therethrough, as described above. Thus, in this preferred embodiment, there is no need for a separate needle and ejector pin, as in the other embodiments described herein.

Fig. 6 is a schematic, sectional illustration showing still another preferred embodiment of the present invention, in which two needles 80 and 82 are simultaneously propelled into bone 50. Needles 80 and 82 preferably comprise superelastic material, formed in a suitably curved shape as shown in the figure. The needles are oriented and aimed so that as they are propelled into the bone, they form respective curved partial channels 84 and 86, which meet at a point 88 to form a single channel 52. The needles are then withdrawn, and the thread is threaded through the



channel, as described above. It will be appreciated that integral, ejectable needles like needle 76 in Fig. 5 could alternatively be used in place of needles 80 and 82.

Needles 80 and 82 are preferably propelled into bone 50 by a double-barreled insertion gun 90, for example as described in the 5,520,700 patent. Gun 90 comprises two barrels 94 and 96, which eject needles 80 and 82 respectively, preferably powered by a common propulsion mechanism 92. It should be noted, however, that the double-barreled gun described in the 5,520,700 patent ejects staples into the bone, which staples remain inside the bone and are not normally withdrawn therefrom.

The preferred embodiment of the present invention illustrated in Fig. 6 is useful in preventing cracking and chipping of bone 50, which may occur particularly in the vicinity of exit hole 54. Since partial channels 84 and 86 have entrance holes, but no exit holes, cracking and chipping are less likely.

Reference is now made to Figs. 7A and 7B, which illustrate schematically, in partly sectional view, an alternative preferred embodiment of the present invention in which the head of a needle 100 comprises a miniature drill bit 102 at tip 104 of the needle for drilling a hole through a bone, rather than producing the hole by percussive impact as in the preceding preferred embodiments. Drill bit 102 preferably comprises abrasive material having an olive-type shape, as is known in the art and used commonly in dental drills. Alternatively, bit 102 may comprise a standard or screw-type drill, which helps advance the drill as it rotates, as are also known in the art. Preferably, bit 102 has a radial diameter that is generally equal to or less than the diameter of needle 100. Alternatively, bit 102 may have a larger diameter than needle 100, to clear the way for the needle to enter the bone.

Bit 102 is driven to rotate by a flexible rotary drive wire 106, passing through a lumen 108 in needle 100. Wire 106 and needle 100 are attached to an insertion driver 110, at the end of the needle opposite tip 104. Driver 110 comprises a rotary mechanism 112, which is coupled to rotate drive wire 106, thereby rotating bit 102. In addition, driver 110 preferably comprises a retractable barrel 114, coupled to springs 116, which urge the barrel forward, toward tip 104 of needle 100. Preferably, the driver is battery operated and disposable, for single-patient use.

Preferably, needle 100 comprises superelastic material, for example, Nitinol, or other highly elastic material known in the art. Needle 100 is formed in a curved shape, but is straightened during insertion into barrel 114, as shown in Fig. 7A. Bit 102 is brought into contact with a bone, and mechanism 112 is activated to rotate the bit and drill into the bone. As needle 100 begins to penetrate the bone, barrel 114 contacts the bone at the end of the barrel near tip 104 of the needle, and the barrel is thus pressed gradually back into the body of driver 110 against springs 116.

As shown in Fig. 7B, as needle 100 exits barrel 114, the needle resumes its curved shape, thus causing bit 102 to drill a curved channel through the bone.

Fig. 7C illustrates schematically an alternative preferred embodiment of the present invention, similar to that shown in Figs. 7A and 7B, except that here drill bit 102 has a greater radial diameter than needle 100. The larger drill bit is useful in that by creating a larger channel through the bone, it makes for easier passage of the needle therethrough.

It will be appreciated that in alternative embodiments of the present invention, insertion driver 110 may have a curved barrel, similar to curved barrel 42 of gun 40, shown in Fig. 2C.

Fig. 8 is a schematic, sectional illustration showing the use of needle 100, together with drill bit 102 and insertion tool 110, as in Figs. 7A and 7B, to create curved channel 52 through a generally flat bone 120, for example a pubic bone. Bone 120 comprises a hard cortex 122, which encloses a softer medulla 124. Bit 102 first drills entrance hole 56 through cortex 122 into medulla 124. The curvature of needle 100 causes bit 102 to turn within the medulla back toward the inner surface of cortex 122, where it then drills exit hole 54.

After channel 52 is drilled, needle 100 and bit 102 are preferably withdrawn through entrance hole 56, leaving channel 52 empty for insertion of thread 22 therethrough.

Alternatively, needle 100 and wire 106 may be detached from tool 110 and pulled out forward, through exit hole 54. Preferably, thread 22 is attached to needle 100, for example by feeding the thread through a hole in needle as described above with reference to other preferred embodiments of the present invention. Then, as the needle is pulled through channel 52, it simultaneously inserts the thread through the channel.

Further alternatively, after channel 52 is formed, and bit 102 protrudes out through exit hole 54, wire 106 is detached from mechanism 112, and bit 102 and wire 106 are together drawn out of bone 120, leaving needle 100 in place. Needle 100 may then be withdrawn via entrance hole 56, or alternatively, left in place inside the bone, in which case thread 22 is inserted through lumen 108 in place of wire 106.

Figs. 9A-9D schematically illustrate another method and apparatus for forming a curved channel through a bone and passing a thread through a channel, in accordance with a preferred embodiment of the present invention. As shown in Fig. 9A in a sectional view, a curved needle 132 and a generally straight needle 140 are mutually aligned at the surface of a bone 130, and needle 132 is then propelled into the bone, forming a curved partial channel 138 therein. Needle 140 is preferably a suture-passing needle, having a notched head 142, through which a suture 144 is passed. Suture 144 preferably comprises a wire suture, as is known in the art, so as to resist tearing during the insertion process.

Needle 132 preferably comprises superelastic material and is fired into the bone by a suitable insertion gun, as described above. The insertion gun preferably comprises either a double-barreled gun, like gun 90 shown in Fig. 6, which drives both needle 132 and needle 140 into the bone. Alternatively, separate guns, may be used to insert the two needles. In either case, needle 132 is inserted first, as shown in Fig. 9A.

Fig. 9B is a schematic illustration of needle 132, as seen in the plane of Fig. 9A, i.e., from the general position of needle 140. Needle 132 comprises a relatively wide, elongated eye 136, generally adjacent to the needle's head 134. The eye is large enough and is so aligned that needle 140 can pass therethrough, as described below.

5 As shown in Fig. 9C, after needle 132 is in place, needle 140 is inserted into bone 130, forming a partial channel 146 and passing through eye 136 of needle 132. Then, as shown in Fig. 9D, needle 140 is withdrawn, leaving suture 144 in eye 136. When needle 132 is then withdrawn, it pulls the suture out through partial channel 138, so that the suture is threaded into and out of bone 130 through the entire curved channel that is formed of partial channels 138 and  
10 146. If suture 144 comprises a wire suture, as described above, it may then be used to pull another suture thread through the curved channel, for use in fixing tissue to the bone, for example.

Fig. 10 is a schematic, sectional illustration showing a suture passer 150, which may be used in place of needle 140 in the procedure of Figs. 9A-9D, in accordance with a preferred  
15 embodiment of the present invention. Suture passer 150 comprises an elongate shaft 152, held in a generally cylindrical sleeve 154, such that the shaft can move longitudinally within the sleeve. Shaft 152 includes a head 156 at a distal end of the shaft, for penetrating into bone 130, and an eye 158 adjacent head 156.

In order to pass suture 144 into the bone, the suture is inserted into eye 158, while shaft  
20 152 is held in the position relative to sleeve 154 that is shown in Fig. 10. The shaft is then pulled proximally (to the left in Fig. 10) through sleeve 154, until head 156 meets the distal end of the sleeve, whereupon the suture is grasped firmly and retained within eye 158. In this configuration, suture passer 150 is propelled into bone 130 and through eye 136 of needle 132. Shaft 152 is then pushed distally through sleeve 154 to release the suture in position, and the  
25 suture passer is withdrawn from the bone, as described above.

Figs. 11A and 11B are schematic, sectional illustrations showing another suture passer 160, in respective open and closed configurations thereof, in accordance with an alternative preferred embodiment of the present invention. Suture passer 160 is used in place of needle 140 in a manner substantially similar to that described above with reference to suture passer 150.

30 Suture passer 160 comprises a shaft 162 having bifurcated heads 164 and 166, with a gap 168 between the heads. Shaft 162 is movably held within a sleeve 163. As shown in Fig. 11A, to insert suture 144 into suture passer 160, shaft 162 is pushed distally through sleeve 163, so that heads 164 and 166 separate, and gap 168 opens. The suture is inserted in the gap, and shaft 162 is then drawn back proximally, as shown in Fig. 11B, so that heads 164 and 166 are pulled  
35 together, closing gap 168 and holding the suture firmly. Once the suture has been passed to a desired position, suture passer 160 is returned to the open configuration of Fig. 11A, and the suture is released.

Further alternatively, an unthreaded straight needle may be used in place of needle 140 for producing channel 146 in the bone. The needle is then removed, and a thread is passed through the channel and through eye 136 using a separate suture passes. In this case, it may not be necessary to use a wire suture during the insertion, but in other respects the method of passing the thread through the bone is substantially similar to that described above.

In some preferred embodiments of the present invention, the devices and methods described above are used in minimally-invasive surgical treatment of urinary stress incontinence in a female subject.

Fig. 12 is a schematic, partly sectional representation of such a preferred embodiment. As Fig. 9 shows, the barrel of an insertion tool 182, or alternatively of insertion tool 110, insertion gun 30 or insertion gun 40, is preferably inserted into the vagina 184 of a female subject 180. The tool or gun is used in conjunction with a suitable needle, in accordance with preferred embodiments of the present invention described above, to create two channels 52 in the posterior side of the subject's pubic bone 170, one channel on either side of the urethra.

Fig. 13 is a schematic illustration of the posterior side of pubic bone 170 (viewed from below, relative to the view shown in Fig. 9), showing the next steps in the surgical treatment. Pubic bone 170 includes right and left portions separated by the symphysis pubis 186 and surrounded by abdominal tissue 188. Suture threads 22 are threaded through both of channels 52, for use in suspending the subject's bladder neck and proximal urethra. This insertion can be performed directly on the posterior pubic bone or through the vaginal wall without any surgical cuts.

In one preferred embodiment of the present invention, the ends of thread 22 protruding from entrance hole 56 and exit hole 54 of each of channels 52 are tied together so as to secure prolapsed periurethral and/or peri-bladder neck tissue to the posterior side of the pubic bone. Securing the prolapsed tissue in this manner effectively suspends the bladder neck and alleviates the subject's incontinence, without the necessity for open abdominal surgery. This procedure, by providing a distance between the entrance and exit holes of the thread within the pubic bone, is similar to the bladder neck suspension procedure described in the 5,520,700 patent and the above mentioned PCT patent applications, but has the additional advantage of alleviating the need to leave four anchors within the bone.

In another preferred embodiment of the present invention, a pubovaginal sling, preferably comprising bovine pericardium, is inserted below the proximal urethra and bladder neck. Alternatively, as is known in the art, the sling may comprise fascia dissected from the patient's body, or Gore-tex fabric or other synthetic material. The ends of the sling are secured to the posterior side of the pubic bone by tying together the ends of threads 22 around the ends of the sling or suturing them to the ends of the sling, thereby suspending the subject's bladder neck and alleviating incontinence, similarly without the necessity for open abdominal surgery.

It will be appreciated that the preferred embodiments described above are cited by way of example, and the full scope of the invention is limited only by the claims.

## CLAIMS

1. Apparatus for inserting a suture thread through a curved channel in a bone, comprising:  
a curved needle, having a head and a shank; and  
an insertion tool, into which the needle is loaded, and which forces the needle into the  
5 bone, such that the needle forms the curved channel, passing through the bone.
2. Apparatus according to claim 1, wherein the needle is adapted to be removed from the curved channel.
3. Apparatus according to claim 1 or 2, wherein the head of the needle is asymmetrical.
4. Apparatus according to any of claims 1-3, wherein the needle comprises superelastic  
10 material.
5. Apparatus according to claim 4, wherein the needle is substantially straightened when loaded into the tool.
6. Apparatus according to claim 4, wherein the needle has a predetermined outer diameter, and wherein the tool comprises a generally straight barrel into which the needle is loaded, the  
15 barrel having an inner diameter substantially greater than the outer diameter of the needle, such that the needle is partially straightened when loaded into the barrel.
7. Apparatus according to claim 6, wherein the needle is forced into the bone at an angle dependent on the difference between the inner diameter of the barrel and the outer diameter of the needle.
8. Apparatus according to any of claims 1-4, wherein the tool comprises a curved barrel,  
20 into which the needle is loaded.
9. Apparatus according to any of the preceding claims, wherein the needle comprises a hole, through which the thread is inserted.
10. Apparatus according to any of the preceding claims, wherein the thread is crimped to the  
25 needle.
11. Apparatus according to any of the preceding claims, wherein the head of the needle is detachable from the shank.
12. Apparatus according to any of the preceding claims, wherein the shank comprises an outer wall, which defines and encloses a lumen therein, through which the thread is passed.
13. Apparatus according to any of the preceding claims, wherein the insertion tool comprises  
30 an insertion gun, which propels the needle into the bone by percussive impact.
14. Apparatus according to any of claims 1-12, wherein the head of the needle comprises a drill bit, and wherein the insertion tool comprises a rotary drive mechanism, which causes the drill bit to rotate, so as to drill the curved channel in the bone.

15. Apparatus according to claim 14, and comprising a flexible drive wire within the needle, which couples rotary motion from the drive mechanism to the drill bit.
16. Apparatus according to claim 14 or 15, wherein the insertion tool comprises a retractable barrel, into which the needle is loaded.
- 5 17. Apparatus for inserting a suture thread through a curved channel in a bone, comprising:  
two needles, at least one of which is curved; and  
one or more insertion tools, into which the two needles are loaded, and which propel the  
needles into the bone,  
wherein each of the needles is adapted to form and be removed from a respective partial  
10 channel in the bone, which partial channels meet to form the curved channel, passing through the  
bone.
18. Apparatus according to claim 17, wherein the at least one curved needle comprises  
superelastic material.
19. Apparatus according to claim 17 or 18, wherein the one or more insertion tools comprise  
15 a double-barreled insertion gun.
20. Apparatus according to any of claims 17-19, wherein one of the two needles comprises  
an eye, through which the other of the needles passes.
21. Apparatus according to any of claims 17-20, wherein one of the two needles comprises a  
suture passer, which inserts a suture into the channel, where it is received by the other of the two  
20 needles.
22. Apparatus according to claim 21, wherein the suture passer comprises a sleeve and a  
shaft longitudinally movable within the sleeve, the shaft having a head with an opening therein  
for receiving the suture, such that by moving the shaft within the sleeve, the suture is grasped in  
the opening.
- 25 23. A method for inserting a suture thread through a bone, comprising:  
forming a curved channel through the bone; and  
inserting the thread through the channel.
24. A method according to claim 23, wherein forming the curved channel through the bone  
comprises drilling through the bone.
- 30 25. A method according to claim 23 or 24, wherein forming the curved channel through the  
bone comprises forcing at least one curved needle through the bone and removing the needle  
from the bone.
26. A method according to claim 25, wherein forcing the needle through the bone comprises  
percussively propelling the needle through the bone.

27. A method according to claim 25 or 26, wherein removing the needle from the bone comprises pulling all or a part of the needle through the channel in the direction in which it was propelled thereinto.
28. A method according to and of claims 25-27, wherein removing the needle from the bone comprises withdrawing all or a part of the needle from the channel in the direction from which it was forced thereinto.
29. A method according to any of claims 25-28, wherein the at least one needle comprises a head part and a shank part, and wherein removing the needle from the bone comprises detaching the head part from the shank part.
30. A method according to any of claims 25-29, wherein inserting the thread through the channel comprises attaching the thread to the needle.
31. A method according to claim 23 or 24, wherein forming the curved channel comprises propelling a curved needle, having a central lumen, through the bone, and wherein inserting the thread through the channel comprises passing the thread through the lumen.
32. A method according to any of claims 23-31, wherein forming the curved channel through the bone comprises forming a channel comprising generally adjacent entrance and exit holes and following a curved path, connecting the entrance and exit holes, through the medulla of the bone.
33. A method according to any of claims 23-32, wherein forming the curved channel through the bone comprises forming a channel that enters the bone at a predetermined angle substantially different from 90° relative to an outer surface of the bone.
34. A method according to any of claims 23-33, wherein forming the curved channel comprises forming two partial channels, which meet inside the bone.
35. A method according to claim 34, wherein forming the two partial channels comprises forcing two needles into the bone, at least one of which needles is curved.
36. A method according to claim 35, wherein inserting the thread through the channel comprises passing the thread into one of the two partial channels using a first one of the two needles, and pulling the thread through the channel using a second one of the two needles.
37. A method according to claim 36, wherein passing the thread using the first one of the two needles comprises passing the first one of the needles through an eye in the second one of the needles.
38. A method for treating incontinence in a female subject, comprising:  
transvaginally inserting first and second suture threads through the pubic bone, wherein the first and second suture threads are inserted on opposite sides of the subject's urethra; and  
tying the extremities of each of the threads so as to suspend tissue to the pubic bone.



39. A method for treating incontinence in a female subject, comprising:

transvaginally forming a curved channel, comprising generally adjacent entrance and exit holes and following a curved path, connecting the entrance and exit holes, through the medulla of the pubic bone;

5 inserting first and second suture threads through the channel on the posterior side of the bone, wherein the first and second suture threads are inserted on opposite sides of the subject's urethra;

inserting a sling transversely below the subject's urethra, so that the ends of the sling are in respective proximity to the first and second sutures in the pubic bone; and

10 tying the threads, so as to secure the ends of the sling to the pubic bone.

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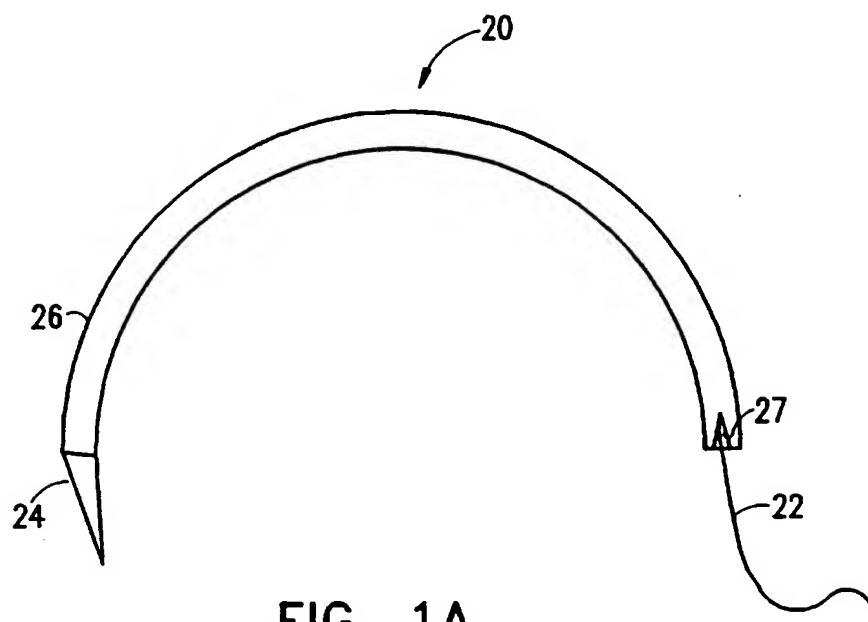


FIG. 1A

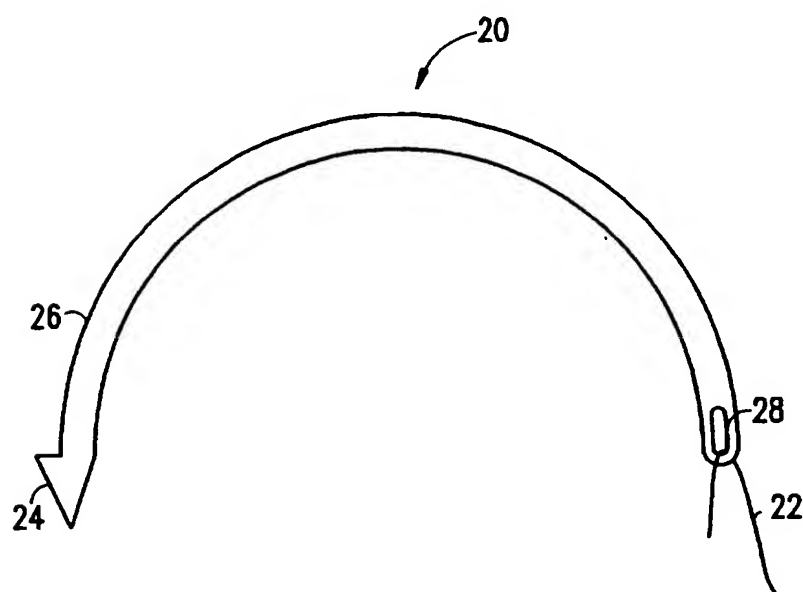


FIG. 1B

FIG. 2B

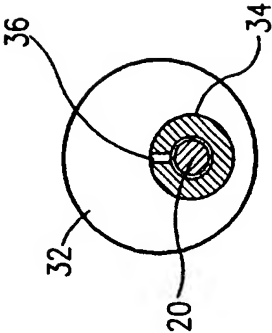
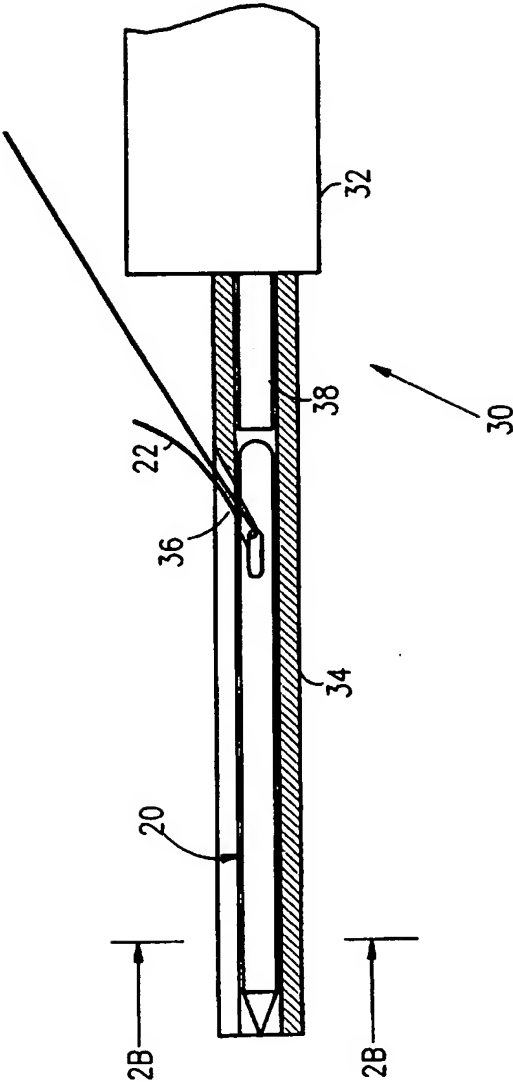


FIG. 2A



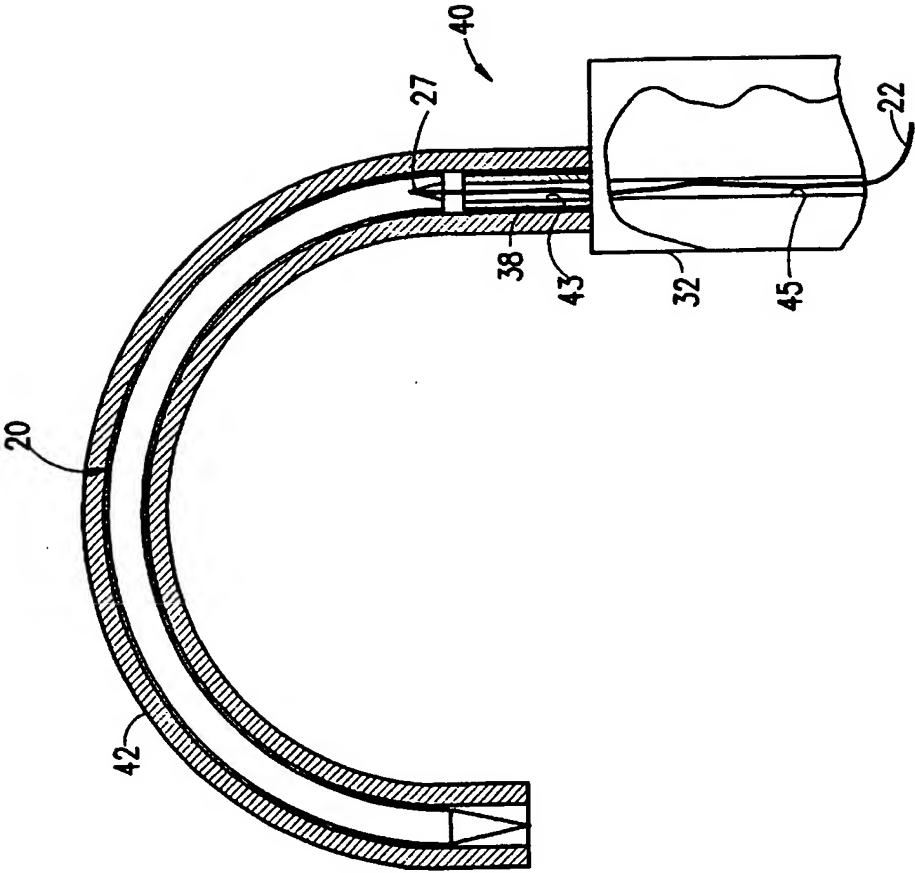
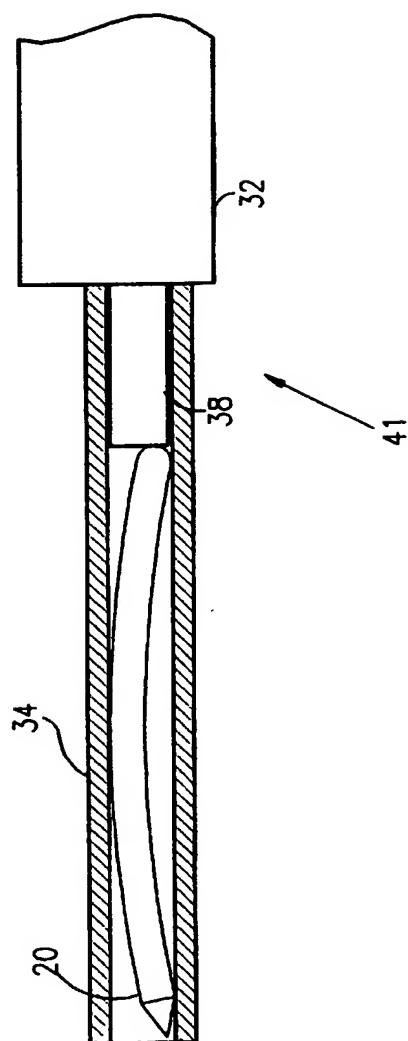


FIG. 2C

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FIG. 2D



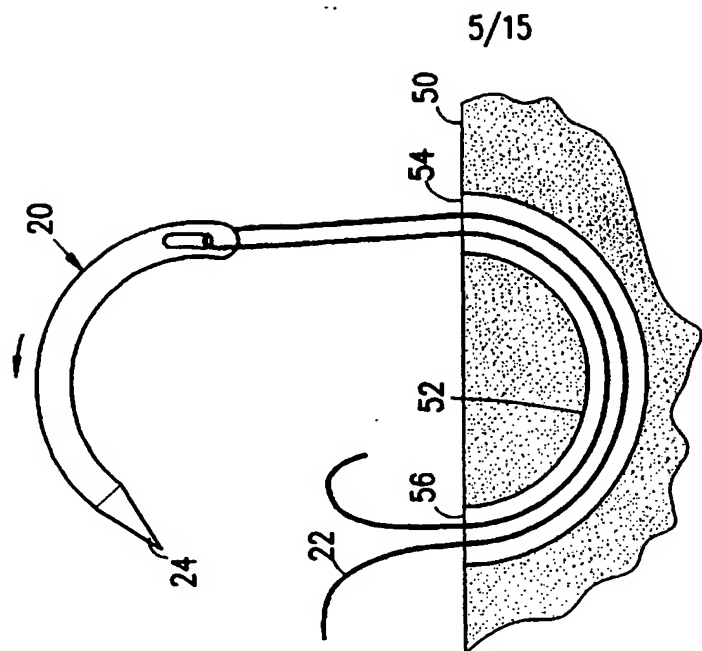


FIG. 3A

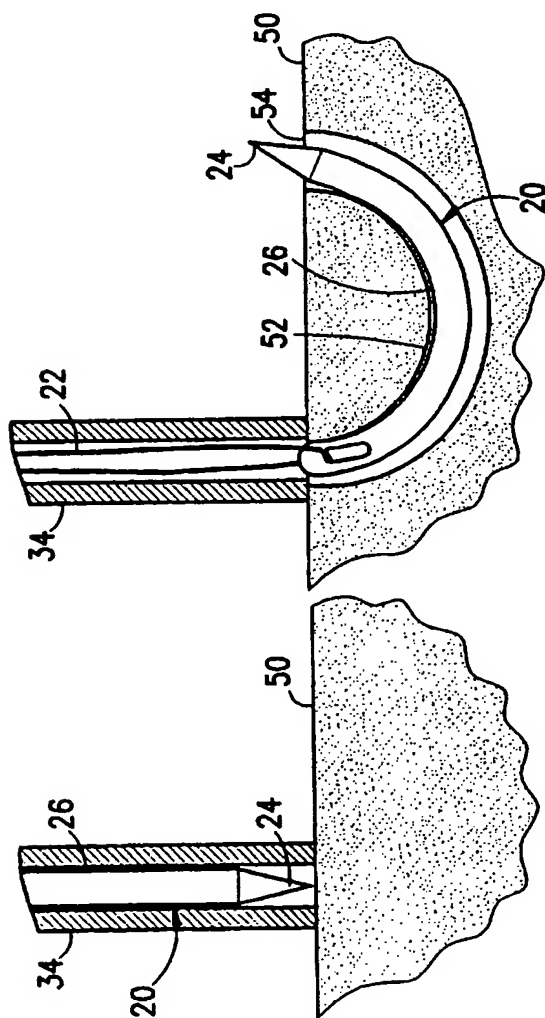


FIG. 3B

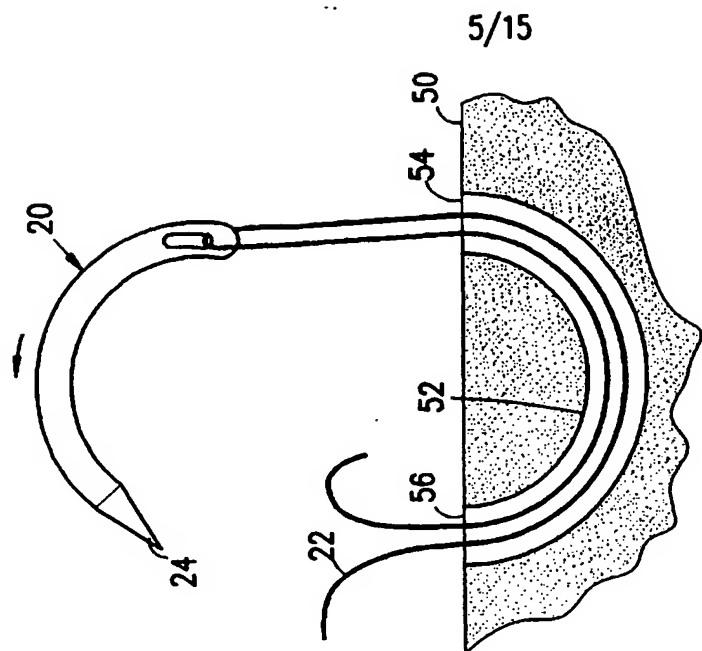


FIG. 3C

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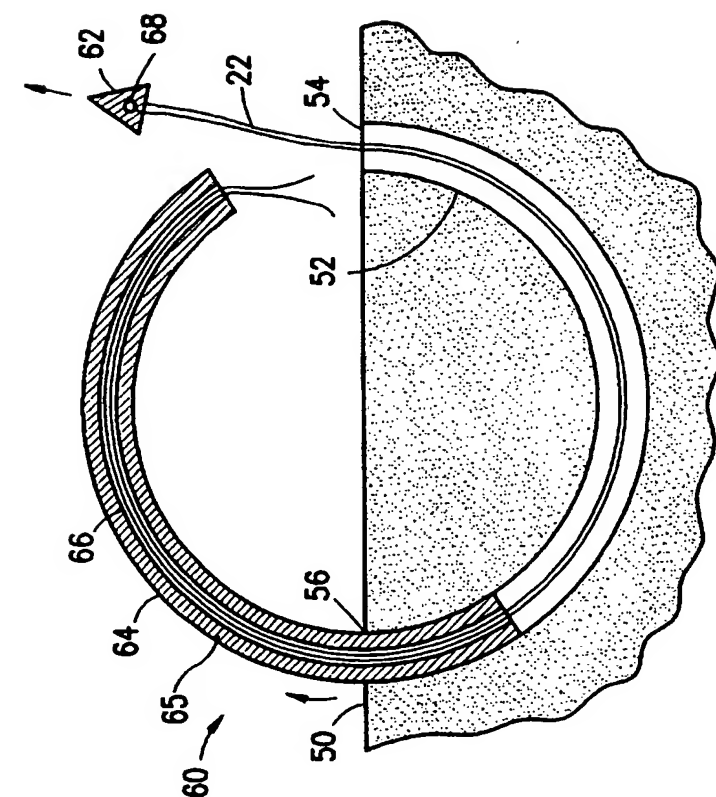


FIG. 4B

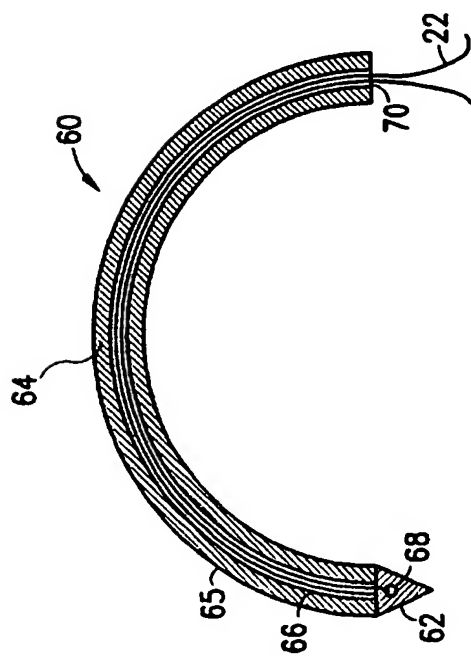


FIG. 4A

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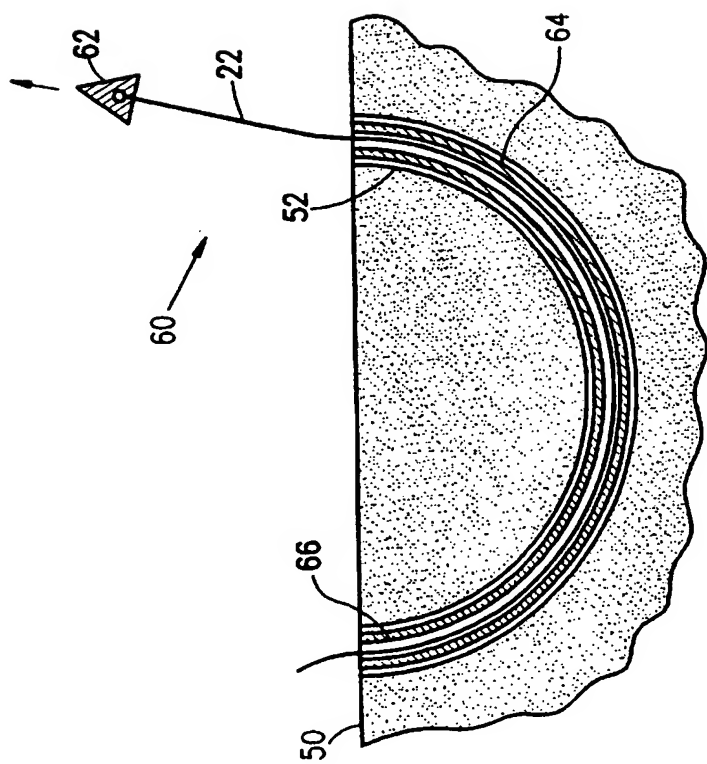


FIG. 4C

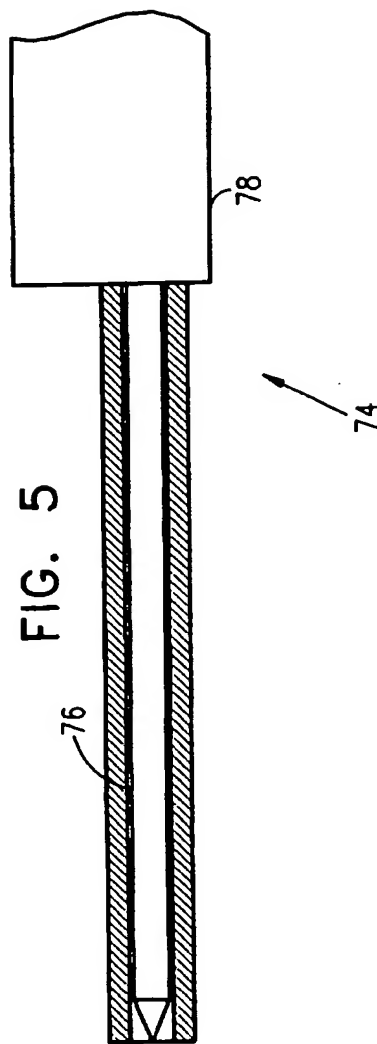
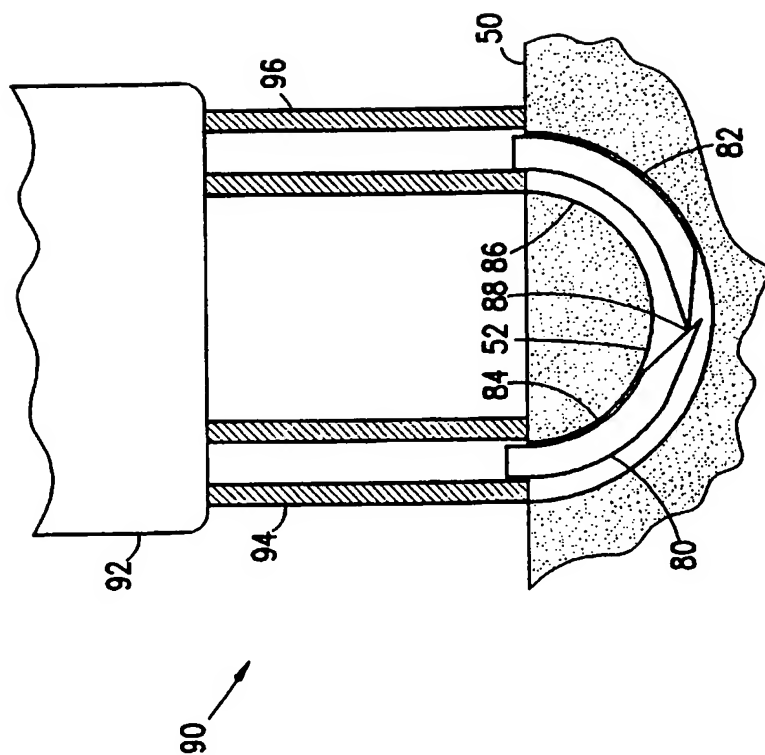


FIG. 5



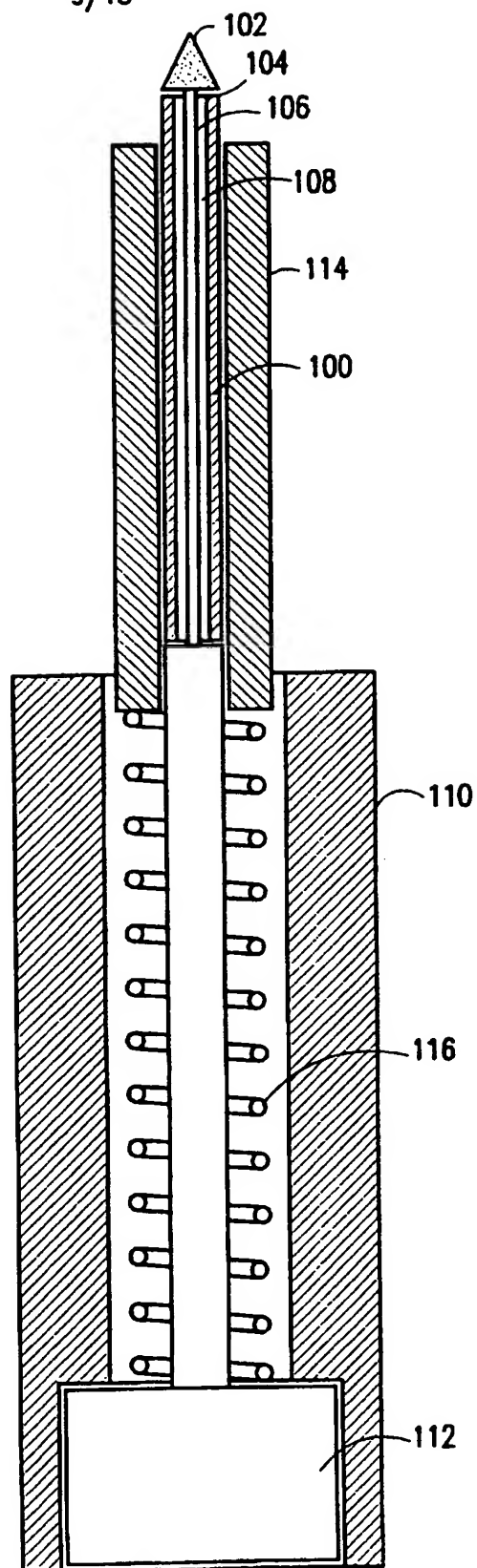
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FIG. 6



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FIG. 7A





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FIG. 7C

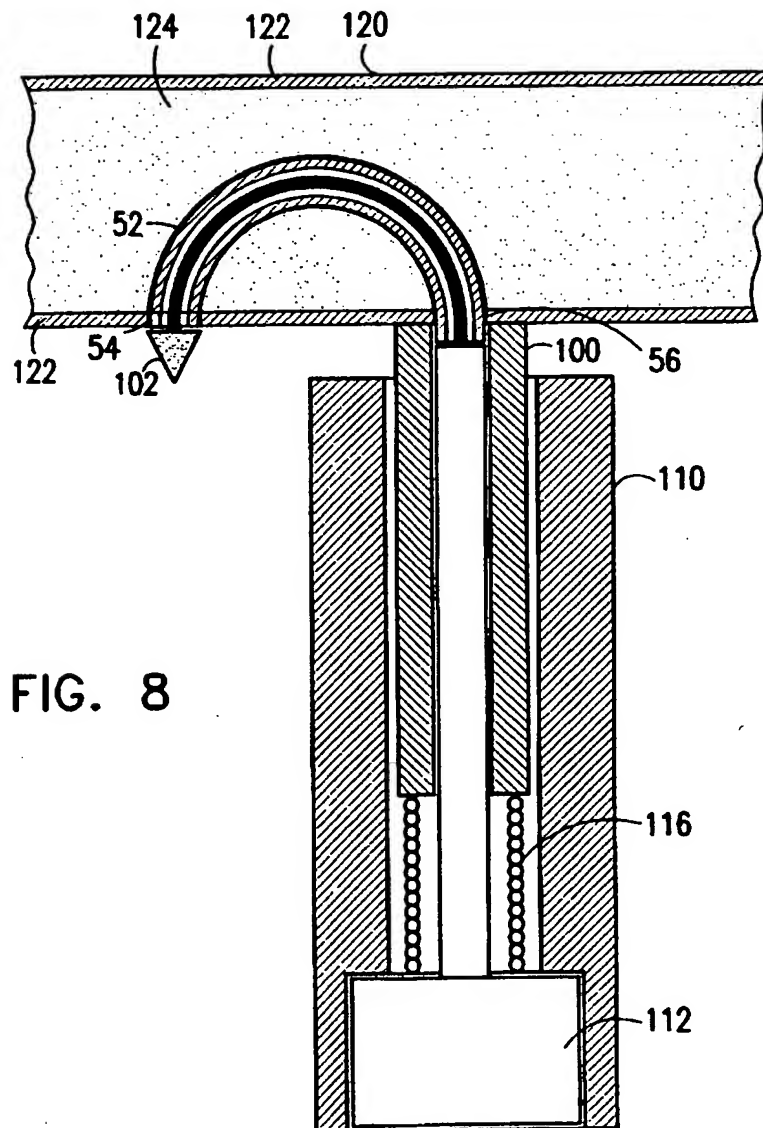
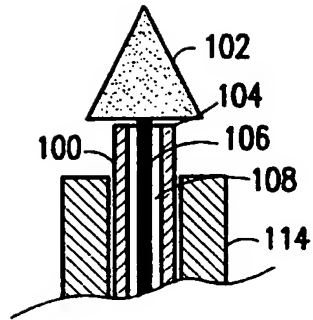


FIG. 8

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FIG. 9A

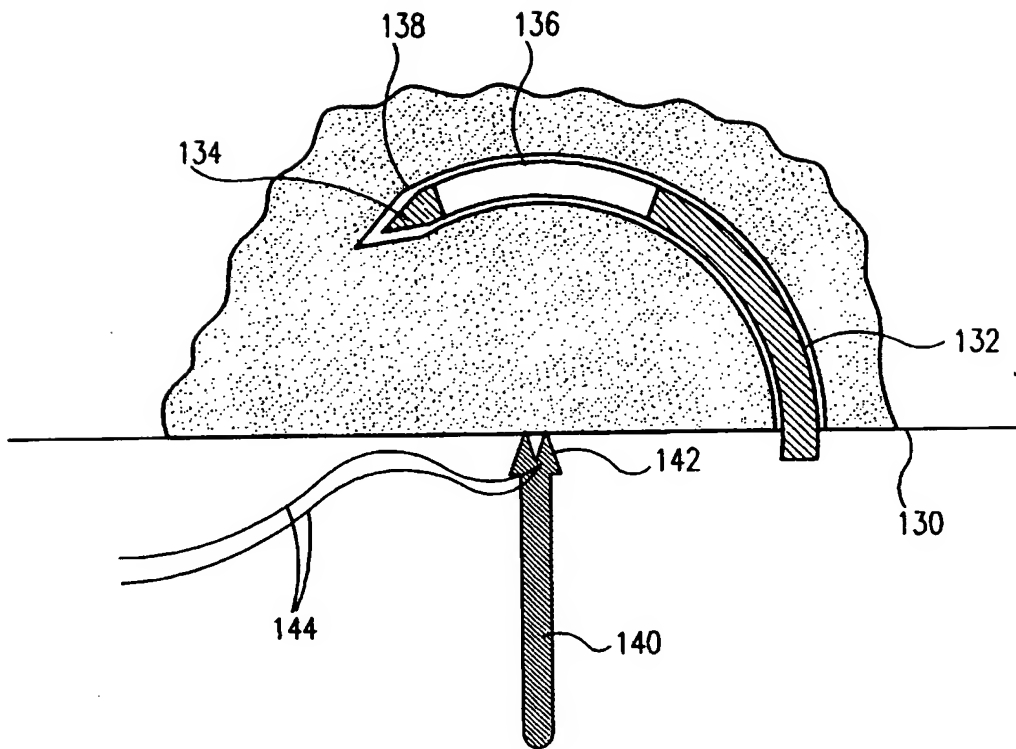
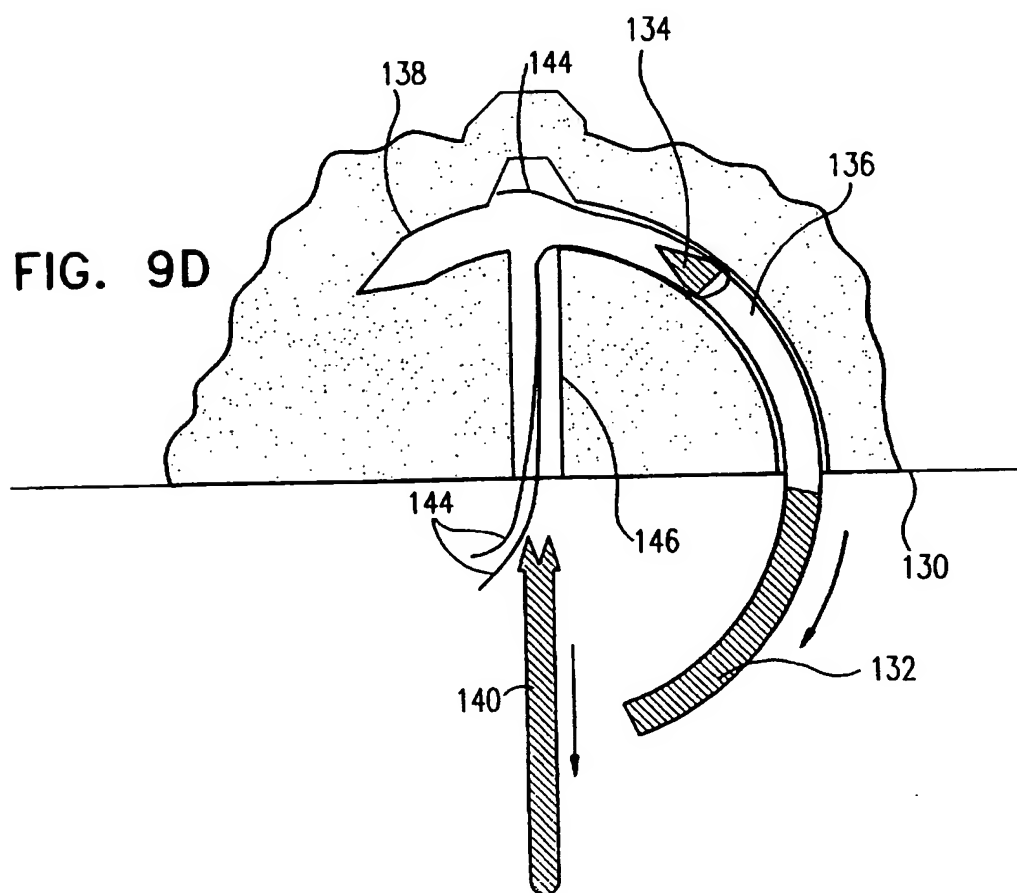
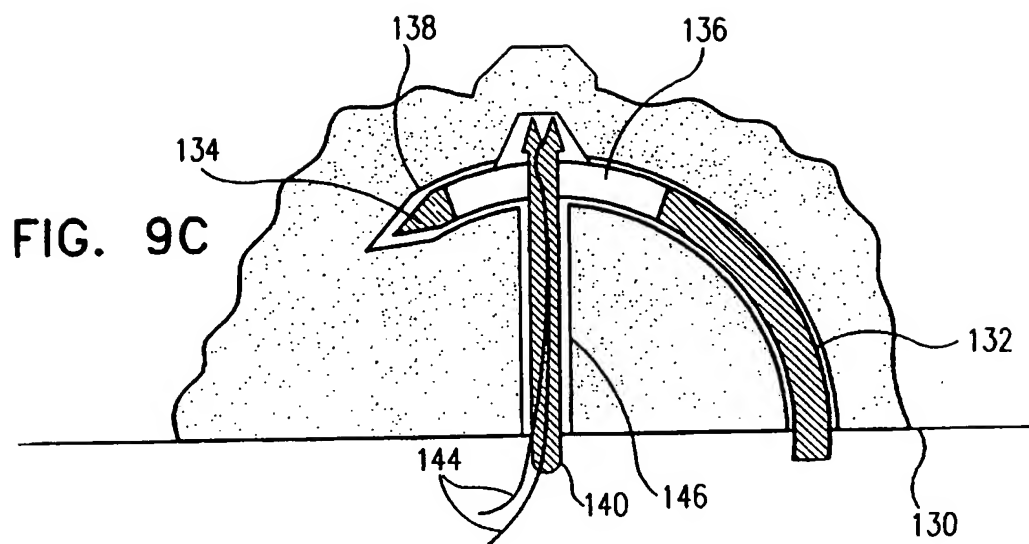


FIG. 9B



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FIG. 10

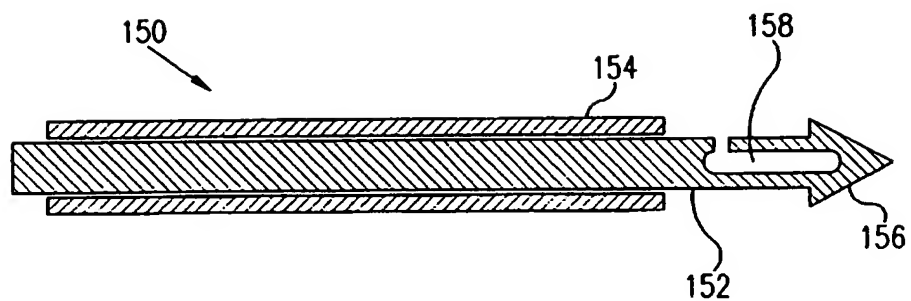


FIG. 11A

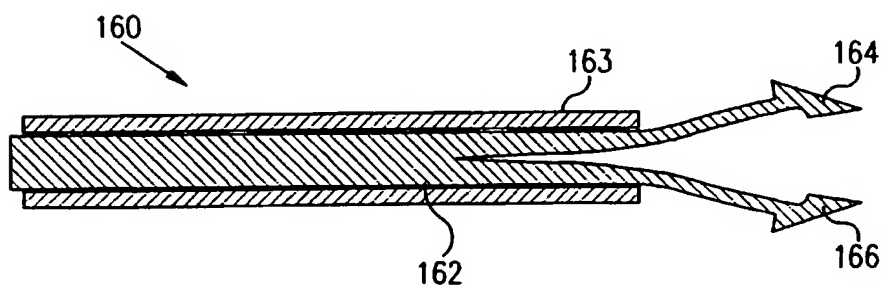
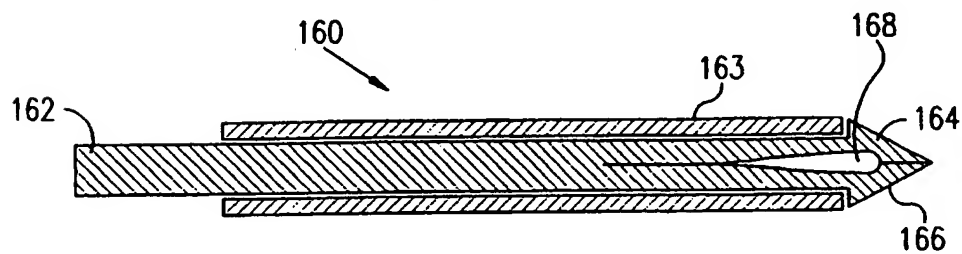


FIG. 11B



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FIG. 12

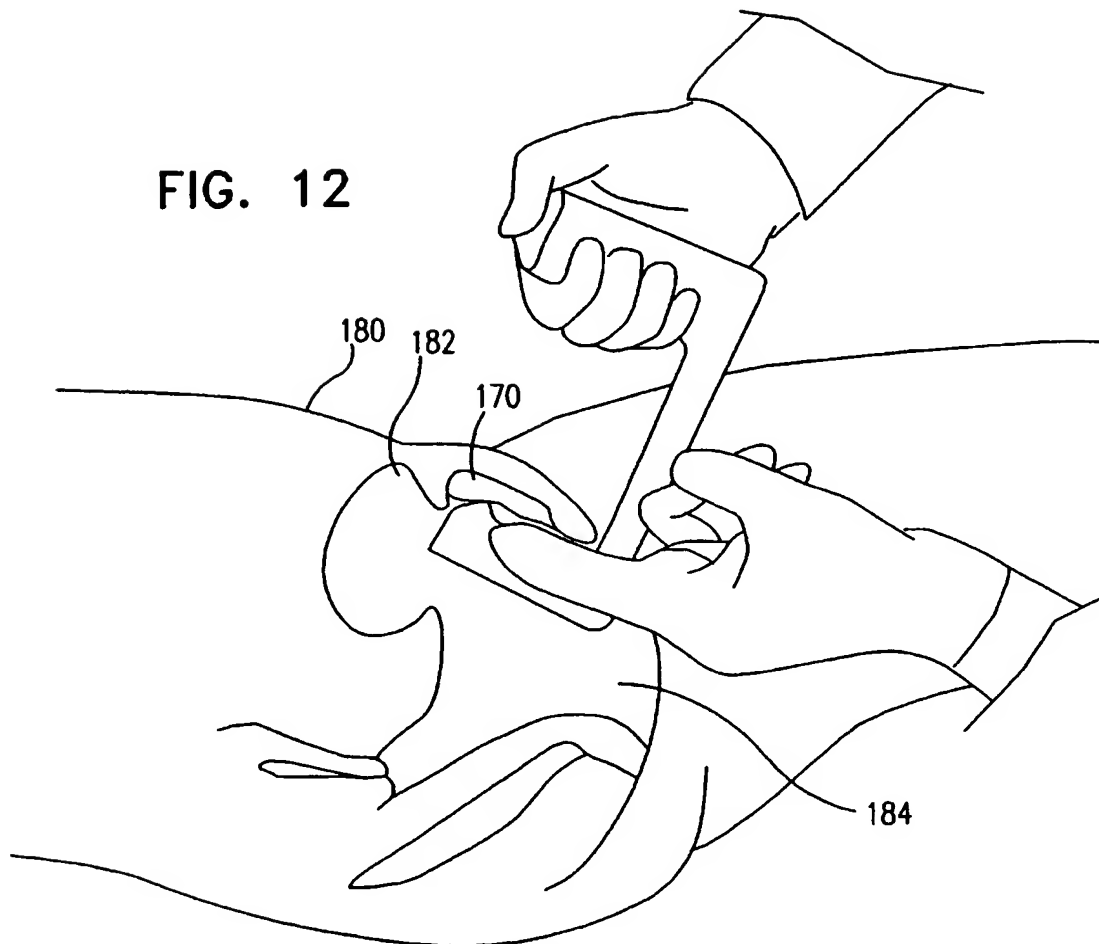
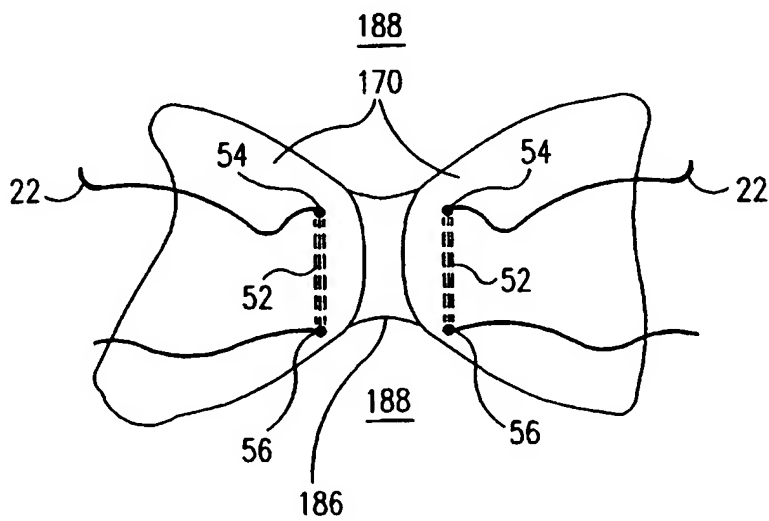


FIG. 13





## INTERNATIONAL SEARCH REPORT

Internat. Application No  
PCT/IL 97/00185

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61B17/16 A61B17/04 A61B17/064		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61B A61F		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 520 700 A (BEYAR) 28 May 1996 cited in the application see column 3, paragraph 3; figures 1-5,9-11,14	1,3, 8-11,13
A	see column 3, paragraph 7 ---	17,19
X	US 5 250 055 A (MOORE) 5 October 1993  see column 2, line 52 - column 3, line 26; figures 1,3,7A,8, ---	1-7,9, 17-21
X	US 4 265 231 A (SCHELLER) 5 May 1981 see column 3, last paragraph ---	1,14,15
Y	US 4 541 423 A (BARBER) 17 September 1985  see abstract; figures 1,3,5 ---	1,2,4,5, 8-12, 14-16
-/--		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		<input checked="" type="checkbox"/> Patent family members are listed in annex.
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p>		
Date of the actual completion of the international search  7 October 1997		Date of mailing of the international search report  28. 10. 97
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  Barton, S

# INTERNATIONAL SEARCH REPORT

Internat. Application No  
PCT/IL 97/00185

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 04853 A (TAHOE) 22 February 1996  see figures 1,3 ---	1,2,4,5, 8-12, 14-16
A	US 4 941 466 A (ROMANO) 17 July 1990 see column 2, paragraph 3 - column 3, paragraph 1; figure 3 ---	17,19
A	EP 0 481 685 A (COOK) 22 April 1992 see figures 1,4,7 ---	6
A	US 5 242 448 A (PETTINE) 7 September 1993 see figures 1,2 ---	6
A	EP 0 478 949 A (USSC) 8 April 1992 see the whole document -----	12

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IL 97/00185

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 23-39  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IL 97/00185

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5520700 A	28-05-96	IL 103737 A CA 2102995 A DE 69308000 D DE 69308000 T EP 0599772 A	18-02-97 14-05-94 20-03-97 22-05-97 01-06-94
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US 5242448 A	07-09-93	NONE	
EP 478949 A	08-04-92	US 5368595 A CA 2049103 A,C CA 2178970 A DE 69124900 D DE 69124900 T ES 2098288 T US 5382257 A	29-11-94 07-03-92 07-03-92 10-04-97 24-07-97 01-05-97 17-01-95